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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,649	07/28/2003	Lena Edelman	02356.0083	4213
22852	7590	03/31/2006	EXAMINER	
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413			CHEN, STACY BROWN	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 03/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/627,649	Applicant(s) EDELMAN ET AL.	
	Examiner Stacy B. Chen	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35-69 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 35-69 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1648

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-6, 8, 9, 11, 26 and 31, is acknowledged. Claims 1-6, 8, 9, 11, 26 and 31 are cancelled in the response filed January 12, 2006. New claims 35-69 are pending. Upon further consideration of the claimed invention, the following new restriction is set forth.

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Claims 35-39, 45, 60 and 61 link(s) inventions I and II. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 35-39, 45, 60 and 61. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104. Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Art Unit: 1648

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

- Group I, claims 40 and 43, drawn to a method to induce apoptosis using a bifunctional molecule comprising a **Targ-tox** protein. (Linking claims 35-39, 45, 60 and 61 will be examined with this Group.)

If Group I is elected, further restriction is required from claims 40 and 43:

Applicant must elect one Targ from the following:

A. Antibodies

B. Peptides

- If Applicant elects Group B, Peptides, then Applicant must also elect one peptide. The peptide may be a homing peptide, or one of the peptides in Table III.

Applicant must **also** elect one Tox from the following:

C. Peptides

D. Peptidomimetics

- If Applicant elects Group C, Peptides, then Applicant must also elect one peptide from the list in Table I.

Art Unit: 1648

- Group II, claims 41 and 44, drawn to a method to induce apoptosis using a bifunctional molecule comprising a **Targ-save** protein. (Linking claims 35-39, 45, 60 and 61 will be examined with this Group.)

If Group II is elected, further restriction is required from claims 41 and 44:

Applicant must elect one Targ from the following:

E. Antibodies

F. Peptides

- If Applicant elects Group F, Peptides, then Applicant must also elect one peptide. The peptide may be a homing peptide, or one of the peptides in Table III.

Applicant must **also** elect one Save from the following:

G. Peptides

H. Peptidomimetics

- If Applicant elects Group G, Peptides, then Applicant must also elect one peptide from the list in Table II.

- Group III, claim 42, drawn to a method of inducing apoptosis using a bifunctional molecule further comprising a Mitochondrial Localization Sequence (MLS).

Claims 46 and 69 link(s) inventions IV and V. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 46.

Art Unit: 1648

- Group IV, claims 47, 50 and 52, drawn to a chimeric bifunctional molecule, **Targ-tox** molecule. (Linking claims 46 and 69 will be examined with this Group.)

If Group IV is elected, further restriction is required. Applicant must elect one Targ from the following:

I. Antibodies

J. Peptides

- If Applicant elects Group J, Peptides, then Applicant must also elect one peptide. The peptide may be a homing peptide, or one of the peptides in Table III.

Applicant must **also** elect one Tox from the following:

K. Peptides

L. Peptidomimetics

- If Applicant elects Group K, Viral Peptides, then Applicant must also elect one peptide from the list in Table I.

- Group V, claims 48, 51 and 53, drawn to a chimeric bifunctional molecule, **Targ-save** molecule. (Linking claims 46 and 69 will be examined with this Group.)

If Group V is elected, further restriction is required. Applicant must elect one Targ from the following:

M. Antibodies

N. Peptides

Art Unit: 1648

- If Applicant elects Group M, Peptides, then Applicant must also elect one peptide. The peptide may be a homing peptide, or one of the peptides in Table III.

Applicant must **also** elect one Save from the following:

O. Peptides

P. Peptidomimetics

- If Applicant elects Group O, Peptides, then Applicant must also elect one peptide from the list in Table II.
- Group VI, claim 49, drawn to a chimeric bifunctional molecule further comprising a Mitochondrial Localization Sequence (MLS).
- Group VII, claim 54 and 55, drawn to a vector encoding chimeric bifunctional molecule.
- Group VIII, claim 56, drawn to a cancer cell having a tumor associated antigen on the surface thereof to which is bound the chimeric bifunctional molecule.
- Group IX, claims 57 and 58, drawn to a monoclonal antibody and hybridoma cell line producing the antibody.
- Group X, claim 59, drawn to a method of determining the presence of a cancer cell having a tumor-associated surface antigen, comprising contacting a biological sample with a chimeric, bifunctional molecule and detecting binding.
- Group XI, claims 62 and 63, drawn to a method of preventing cell death comprising contacting a biological sample with a **Targ-save** molecule.

Art Unit: 1648

If Group XI is elected, further restriction is required. Applicant must elect one Targ from the following:

Q. Antibodies

R. Peptides

- If Applicant elects Group R, Peptides, then Applicant must also elect one peptide. The peptide may be a homing peptide, or one of the peptides in Table III.

Applicant must **also** elect one Save from the following:

S. Peptides

T. Peptidomimetics

- If Applicant elects Group S, Peptides, then Applicant must also elect one peptide from the list in Table II.
- Group XII, claims 64 and 65, drawn to a method of identifying an agent that interacts with the activity of the PTPC complex using chimeric bifunctional molecule.
- Group XIII, claim 66, drawn to a method to identify *tox*-like mitochondrial antigens.

If Group XIII is elected, further restriction is required. Applicant must elect one Targ from the following:

U. Antibodies

V. Peptides

- If Applicant elects Group V, Peptides, then Applicant must also elect one peptide. The peptide may be a homing peptide, or one of the peptides in Table III.

Art Unit: 1648

Applicant must **also** elect one Tox from the following:

W. Peptides

X. Peptidomimetics

- If Applicant elects Group W, Viral Peptides, then Applicant must also elect one peptide from the list in Table I.

- Group XIV, claim 67, drawn to a method to identify *save*-like mitochondrial antigens.

If Group XIV is elected, further restriction is required. Applicant must elect one Targ from the following:

Y. Antibodies

Z. Peptides

- If Applicant elects Group Z, Peptides, then Applicant must also elect one peptide. The peptide may be a homing peptide, or one of the peptides in Table III.

Applicant must **also** elect one Save from the following:

AA. Peptides

BB. Peptidomimetics

- If Applicant elects Group AA, Peptides, then Applicant must also elect one peptide from the list in Table II.

- Group XV, claim 68, drawn to a method of treatment or of prevention of a pathological infection or disease comprising administering to a patient a pharmaceutical composition comprising a chimeric, bifunctional molecule.

Art Unit: 1648

Applicant's arguments have been carefully considered but fail to persuade. Applicant argues that a method to inhibit apoptosis and a method to prevent apoptosis are not patentably distinct because the inventive concept is the same in both methods: targeting the permeability transition core complex to effect apoptosis. In response to Applicant's argument, the prior art anticipates this feature of targeting the permeability transition core complex to effect apoptosis (see Yarkoni *et al.*). Further, the method of inhibiting apoptosis requires an antiapoptotic molecule, while the method of inducing apoptosis requires an apoptotic molecule. The reagents used in the two methods must differ because their effects on apoptosis are different. Therefore, the methods are patentably distinct.

The asserted special technical feature of the instant claim set is a *tox* molecule or a *save* molecule fused to a target protein. The prior art anticipates this feature. Yarkoni *et al.* (WO 99/45128, cited in IDS) teaches chimeric proteins with cell-targeting specificity and apoptosis-inducing activities (see abstract). Therefore, the claims lack unity of invention.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention. The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Should Applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In

Art Unit: 1648

either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Stacy B. Chen
March 28, 2006